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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,296	06/21/2001	Hsien-Jue (Steve) Chu	AM100221	6853

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WYETH
PATENT LAW GROUP
5 GIRALDA FARMS
MADISON, NJ 07940

EXAMINER	
DEVI, SARVAMANGALA J N	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 06/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/887,296	CHU ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 27-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 27-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

1) Acknowledgment is made of Applicants' amendment filed 03/09/2005 in response to the non-final Office Action mailed 09/10/04.

Status of Claims

2) Claims 1-3, 5, 6-10, 27, 28 and 30 have been amended via the amendment filed 03/09/05.

Claims 11-26 have been canceled via the amendment filed 03/09/05.

Claims 1-10 and 27-30 are pending and are under examination.

Prior Citation of Title 35 Sections

3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Withdrawn

5) The objection to claims 2 and 3 made in paragraph 21 of the Office Action mailed 09/10/04 is withdrawn in light of Applicants' amendments to the claims.

Rejection(s) Withdrawn

6) The rejection of claims 1-10 and 27-30 made in paragraph 15 of the Office Action mailed 09/10/04 under 35 U.S.C § 112, first paragraph, as containing new subject matter, is withdrawn in light of Applicants' amendment to the claims.

7) The rejection of claim 1 made in paragraph 16(a) of the Office Action mailed 09/10/04 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

8) The rejection of claim 3 made in paragraph 16(c) of the Office Action mailed 09/10/04 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants'

amendment to the claim.

9) The rejection of claim 10 made in paragraph 16(d) of the Office Action mailed 09/10/04 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

10) The rejection of claim 7 made in paragraph 16(e) of the Office Action mailed 09/10/04 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

11) The rejection of claim 3 made in paragraph 16(f) of the Office Action mailed 09/10/04 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

12) The rejection of claim 27 made in paragraph 16(g) of the Office Action mailed 09/10/04 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

13) The rejection of claims 28 and 30 made in paragraph 16(h) of the Office Action mailed 09/10/04 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.

14) The rejection of claims, 2, 4-10 and 27-30 made in paragraph 16(i) of the Office Action mailed 09/10/04 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the base claim.

15) The rejection of claims 1-3, 5, 6, 29 and 30 made in paragraph 26 of the Office Action mailed 06/25/03 and maintained in paragraph 10 of the Office Action mailed 09/10/04 under 35 U.S.C § 103(a) as being unpatentable over Casas *et al.* (US 6,100,388, already of record) in view of the DE patent 1793631 (already of record) and Shimada *et al.* (US 5,626,837, already of record), is withdrawn upon further consideration.

16) The rejection of claims 1-3, 5, 6, 9, 29 and 30 made in paragraph 27 of the Office Action mailed 06/25/03 and maintained in paragraph 11 of the Office Action mailed 09/10/04 under 35 U.S.C § 103(a) as being unpatentable over Clements *et al.* (US 6,019,982, already of record) in view of the DE patent 1793631 (already of record) and Shimada *et al.* (US 5,626,837, already of

record), is withdrawn upon further consideration.

17) The rejection of claims 4 and 7 made in paragraph 28 of the Office Action mailed 06/25/03 and maintained in paragraph 12 of the Office Action mailed 09/10/04 under 35 U.S.C § 103(a) as being unpatentable over Casas *et al.* (US 6,100,388, already of record) or Clements *et al.* (US 6,019,982, already of record) as modified by the DE patent 1793631 (already of record) and Shimada *et al.* (US 5,626,837, already of record) as applied to claims 1 and 4, and further in view of Grieve (*Poultry Digest*, November 1992, pp. 28-32, already of record), is withdrawn upon further consideration.

18) The rejection of claim 10 made in paragraph 29 of the Office Action mailed 06/25/03 and maintained in paragraph 13 of the Office Action mailed 09/10/04 under 35 U.S.C § 103(a) as being unpatentable over Casas *et al.* (US 6,100,388, already of record) or Clements *et al.* (US 6,019,982, already of record) as modified by the DE patent 1793631 (already of record), Shimada *et al.* (US 5,626,837, already of record) and Grieve (*Poultry Digest*, November 1992, pp. 28-32, already of record) as applied to claims 1, 6 and 7, and further in view of Roland (US 6,399,074, already of record), is withdrawn upon further consideration.

19) The rejection of claim 8 made in paragraph 30 of the Office Action mailed 06/25/03 and maintained in paragraph 14 of the Office Action mailed 09/10/04 under 35 U.S.C § 103(a) as being unpatentable over Clements *et al.* (US 6,019,982, already of record) as modified by the DE patent 1793631 (already of record), Shimada *et al.* (US 5,626,837, already of record) and Grieve (*Poultry Digest*, November 1992, pp. 28-32, already of record) as applied to claims 1, 6 and 7, and further in view of Frantz *et al.* (US 5,536,496, already of record), is withdrawn upon further consideration.

Rejection(s) Maintained

20) The rejection of claim 2 made in paragraph 16(b) of the Office Action mailed 09/10/04 under 35 U.S.C § 112, second paragraph, as being indefinite, is maintained for reasons set forth therein. Applicants have not addressed this rejection.

21) The rejection of claim 3 made in paragraph 16(i) of the Office Action mailed 09/10/04 under 35 U.S.C § 112, second paragraph, as being indefinite, is maintained for reasons set forth

therein.

22) The rejection of claims 1-7, 9 and 28-30 made in paragraph 17 of the Office Action mailed 09/10/04 under 35 U.S.C § 103(a) as being unpatentable over Brinton *et al.* (WO 99/59626) in view of Strobel *et al.* (US 6,225,304 B1) and Collins *et al.* (US 6,498,008), is maintained for reasons set forth therein and herebelow.

Applicants contend that Brinton *et al.* describe vaccine compositions and methods for immunizing poultry in which the vaccine composition can be mass administered to the poultry through oral intake of water with or without the addition of antibiotic. Applicants further submit that: (a) the goal of the reference is to avoid the drug interactions of live vaccines with antibiotics; (b) it is essential that the vaccine of Brinton *et al.* contain an inactivated bacterin and not live vaccines that are susceptible to antibiotics; (c) Example 4 notes that as the amount of water consumed increases with increasing bird age, the amount of antigen increases, and therefore the amount of immunization that the bird will receive appears to be dependent upon its age and is not shown to be a controllable factor; (d) there is absolutely no teaching or suggestion of how to moderate or improve the amount of vaccine formulation that the bird will consume.

With regard to Strobel *et al.*, Applicants contend that: (a) the reference teaches a solid mixture or aqueous solution of amoxicillin antibacterial agent with a material that aids in its dissolution in water to render it ingestive and palatable; (b) the reference indicates that to enhance the palatability of the solution, one may add flavorings and/**or** artificial sweeteners; and (c) Example 6 demonstrates that the addition of sweetener increases the effective dose per unit weight of the pig.

With regard to Collins *et al.*, Applicants contend that: (a) the reference describes methods for diagnosis of the causative agent of MSD; (b) Collins *et al.* suggest that a MSD vaccine can be administered in a variety of dosage forms and formed into a powder or suspended in an aqueous solution such that it can be added to animal feed or animal's drinking water; (c) Collins *et al.* further suggest that the vaccine powders or solutions can be suitably sweetened or flavored by various known agents to promote the uptake of the vaccine orally by the pig; (d) no viable oral vaccine composition however is revealed or demonstrated; and (e) the examples only show that pigs were intranasally inoculated, the MSD agent was infectious, and antisera were obtained.

Applicants further allege that: (a) there is no illustration of a vaccine formulation that has been effectively and orally administered to the pigs to prevent the production of MSD disease let alone through mass oral administration of pigs; (b) there are no options of sweeteners or flavoring agents described; (c) the bare suggestion that the vaccine solution can be suitably sweetened or flavored without exemplification is not enabling prior art, and it is purely an invitation to experiment further; and (d) the disclosure of Collins *et al.* is not enabling to the ordinary practitioner of how to make and use the instantly claimed method, and it would take undue experimentation to arrive at the claimed method.

Applicants argue that: (a) it is impermissible to pick and choose components from each reference without examining the context of each component in the reference and what the reference actually teaches about those components; (b) in view of Strobel *et al.* exemplifying the importance of the sweetener in providing antibiotics to herds of animals, there is no way the ordinary practitioner would have found the same solution as Applicants when addressing to the same problem; (c) the only reason someone would try the flavoring agent alone is with inventive curiosity, which negates obviousness; and (d) the unexpected criticality of the flavorant additive to the vaccine formulation of the present invention is neither taught nor suggested by the collective art.

Applicants' arguments have been carefully considered, but are not persuasive. As set forth in paragraph 17 of the Office Action mailed 09/10/04, the claims are unpatentable over the disclosure of Brinton *et al.* in view of the teachings of Strobel *et al.* and Collins *et al.* As Applicants readily acknowledge, Brinton *et al.* described methods for immunizing poultry in which the vaccine composition can be mass administered to the poultry through oral intake of water with or without the addition of antibiotic. The goal of Brinton *et al.* is stated in the abstract of the reference to be immunization of poultry by a method that comprises administering a vaccine composition comprising inactivated bacterial organisms to the poultry through oral intake of water. Whether or not Brinton's vaccine is live or inactivated is irrelevant, since the vaccine used in the method of the instant base claim and those dependent therefrom, is not limited to a live or inactivated vaccine, but encompasses both types of vaccine. Whether or not the amount of immunization that the bird will receive is dependent upon its age, and whether or not Brinton *et*

al. disclose how to moderate or improve the amount of vaccine formulation that the bird will consume are irrelevant, since the instant claims do not include such limitations.

As Applicants readily acknowledge, Strobel *et al.* taught that flavorings and/**or** artificial sweeteners may be added to a solid mixture or an aqueous solution in order to enhance the palatability of the mixture or the solution. Applicants' acknowledgement that Collins *et al.* suggested the suitable flavoring of the vaccine powders or solutions by various *known agents* in order to promote the uptake of the vaccine orally by the pig has been noted. Whether or not Collins' vaccine is live or inactivated is irrelevant, since the vaccine used in the method of the instant base claim and those dependent therefrom is not limited to a live or inactivated vaccine, but encompasses both types of vaccine. Applicants are reminded that Collins' reference is not an anticipatory reference, but is applied under 35 U.S.C 103, and therefore the reference of Collins *et al.* does not have to illustrate a vaccine formulation that has been effectively and orally administered to the pigs to prevent the production of MSD disease through mass oral administration of pigs. Since Collins *et al.* expressly taught the suitable flavoring of the vaccine powders or solutions with various *known agents* in order to promote the uptake of the vaccine orally by the pig, there is no need for Collins *et al.* to further describe or exemplify the already *known flavoring agents*. The purpose of adding a flavoring agent to a vaccine, a pharmaceutical or therapeutic composition is not for inventive curiosity as alleged, but for the definitive purpose of 'promoting the uptake of the vaccine orally by the animal'. Contrary to Applicants' argument, the disclosure of Collins *et al.* is fully enabled. The step of flavoring the vaccine powders or solutions using various *art known flavoring agents* does not require undue experimentation, but is well within the realm of routine experimentation, since addition of a flavoring agent to a microbial vaccine has been known in the art since 1960, i.e., since the days of poliomyelitis vaccine. For instance, in 1960, Rea Cox Herald (US 2,966,443) disclosed the addition of cherry fruit flavoring to a live poliomyelitis oral vaccine (see Example 1). See paragraph 26 below which is set forth to document how routine has it been in the art to add a flavoring agent to therapeutic or pharmaceutical compositions.

Applicants have argued as though the applied references were applied under 35 U.S.C. § 102 as anticipatory references. Applicants appear to argue that the combination of references fails

because the prior art does not have anticipatory references regarding all elements of the invention. The argument is not persuasive. At issue is whether the claimed method is obvious over the method disclosed by Brinton *et al.* as modified by Strobel *et al.* and Collins *et al*, given the expressly disclosed motivation of promoting the uptake of the vaccine orally by the animals by adding an art-known flavoring agent. For reasons explained above, the claimed method is *prima facie* obvious over the prior art of record. The Office recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention, where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In the instant case, motivation is found in one or more of the applied reference(s). The rejection stands.

23) The rejection of claim 10 made in paragraph 19 of the Office Action mailed 09/10/04 under 35 U.S.C § 103(a) as being unpatentable over Brinton *et al.* (WO 99/59626) as modified by Strobel *et al.* (US 6,225,304 B1) and Collins *et al.* (US 6,498,008) as applied to claims 7 and 1 above, and further in view of Roland (US 6,399,074, already of record), is maintained for reasons set forth therein and herebelow.

Applicants contend that Roland purely teaches force-feeding the vaccine to the animal by gastric gavage that utilizes the syringe device. Applicants submit that the intratracheal route of Roland does not teach or imply the oral route. Applicants conclude that successful immunization using a syringe to administer the flavored vaccine formulation of the present invention to the mouth of an animal without the animal spitting the dose out cannot be predicted from the forced feeding and gastric gavage of Roland.

Applicants' arguments have been carefully considered, but are not persuasive. As set forth clearly in paragraph 19 of the Office Action mailed 09/10/04, Roland taught vaccinating birds 'by oral gavage' using a feeding device attached to a syringe. Roland does not teach the alleged 'force feeding by gastric gavage'. One of skill in the art readily understands that 'oral gavage' is not the same as 'gastric gavage'. Nothing in Roland indicates that there was dose spitting by the animals following the oral gavage using a syringe. The Office Action at 19 of the Office Action

mailed 09/10/04 did not cite Roland as teaching 'intratracheal route', and did not imply that intratracheal route is oral route. Roland's intratracheal route is unrelated to vaccination, but was used to challenge animals that were already vaccinated by oral administration through a syringe (see first full paragraph in column 18 of Roland). The rejection stands.

24) The rejection of claim 27 made in paragraph 18 of the Office Action mailed 09/10/04 under 35 U.S.C § 103(a) as being unpatentable over Brinton *et al.* (WO 99/59626) as modified by Strobel *et al.* (US 6,225,304 B1) and Collins *et al.* (US 6,498,008) as applied to claims 7 and 1 above, and further in view of Mitani *et al.* (JP 02163064 A), is maintained for reasons set forth therein and herebelow.

Applicants contend that Mitani *et al.* specifically teach a method to obtain apple water having moderate apple flavor as a diluent for alcohol or whiskey. Applicants state that a person working in the veterinary or pharmaceutical field would not consult the reference of Mitani *et al.* to select the crucial water-soluble flavorants to be used in combination with oral vaccine formulations. Applicants submit that even if combined, Strobel *et al.* would teach the ordinary practitioner that to be palatable to animals, the apple flavoring would be insufficient by itself and a sweetener must be included in the vaccine formulation. Applicants state that in sharp distinction, Applicants have demonstrated that the sweetener is not necessary. Applicants contend that quite surprisingly, the claim-recited method can be practiced with the water-soluble flavorant and provide 100% effective protection from disease in the mass vaccination program. Applicants conclude that based on the teachings in the art, one would have no reasonable expectation of success of the claimed method in the absence of the sweetener.

Applicants' arguments have been carefully considered, but are not persuasive. As set forth in paragraph 18 of the Office Action mailed 09/10/04, the step of adding an alternate fruit flavor, such as, an apple flavor to drinking water was well known in the art at the time of the invention. For example, Mitani *et al.* taught the use of apple flavor to flavor drinking water. Mitani *et al.* expressly taught that the use of apple flavored water can **itself** be used as drinking water (see English abstract). Contrary to Applicants' assertion, Strobel *et al.* would not teach the ordinary practitioner that to be palatable to animals, the apple flavoring would be insufficient by itself and a sweetener must be included in the vaccine formulation as alleged, because Strobel *et al.* taught the

use of flavorings and/**or** artificial sweeteners (see lines 12 and 13 in column 5). Therefore, Applicants' statement that one would have no reasonable expectation of success of the claimed method in the absence of the sweetener has no basis. The rejection stands.

25) The rejection of claims 1-8 and 28-30 made in paragraph 20 of the Office Action mailed 09/10/04 under 35 U.S.C § 103(a) as being unpatentable over Bricker *et al.* (*Avian Diseases* 32: 668-673, 1988) in view of Strobel *et al.* (US 6,225,304 B1) and Collins *et al.* (US 6,498,008), is maintained for reasons set forth therein and herebelow.

Applicants contend that Bricker *et al.* show vaccinating turkeys via drinking water with a live *Erysipelothrix* vaccine and indicate that the vaccine provided partial protection against subsequent challenge with the virulent isolate of the same serotype. Applicants acknowledge that Collins *et al.* suggest the flavoring or sweetening of vaccine powders or solutions to promote the uptake of the vaccine orally by the pigs. Applicants argue that: (a) the examples of Collins *et al.* only show intranasal inoculation of pigs with an infectious agent; (b) Collins *et al.* do not demonstrate how to make or use vaccine by successful mass vaccination of animals; (c) there are no examples of sweetening or flavoring agents; (d) since Strobel *et al.* expressly teach that the addition of sweetener increases the effective dose per unit weight of the pig, (e) the collective art would only suggest to the ordinary practitioner that the addition of sweetener to the methods of Bricker *et al.* might improve their experimental results of partial protection against disease; (f) there is absolutely no reason based on the combined art to add only flavoring agents to the turkey's drinking water of Bricker *et al.* and expect improved results, let alone achieve the significant 100% protection exemplified in the present method; and (g) none of the above combinations of references provide the motivation to produce the instant invention and practice the claimed method.

Applicants' arguments have been carefully considered, but are not persuasive. The limitation 'protection' in claim 1 is not limited to full (100%) protection, but encompasses both full and partial protection. In other words, partial protection is not excluded from the scope of the claimed method. Therefore, the vaccine used in the prior art method does not have to provide 100% protection. Contrary to Applicants' assertion, the method claimed in the instant claims is not required to provide 'improved results' or 'significant 100% protection'.

As set forth in paragraph 20 of the Office Action mailed 09/10/04, Bricker *et al.* taught a method of providing protection against erysipelas in turkeys comprising admixing an *Erysipelothrix rhusiopathiae* vaccine (i.e., antigen) with drinking water and administering the vaccine orally to turkeys (see abstract; 'Materials and Methods'; and 'Results'). Bricker *et al.* do not teach the step of admixing a water soluble palatable fruit flavorant, fish flavorant, or meat flavorant with the drinking water vehicle containing the bacterial antigen or vaccine. However, as Applicants readily acknowledge, Collins *et al.* taught the flavoring of vaccine powders or solutions to promote the uptake of the vaccine orally by the pigs. Strobel *et al.* showed the routine and conventional nature of flavoring an animal's drinking water. Strobel *et al.* explicitly taught enhancing the palatability of animals' drinking water by adding a flavoring agent such as strawberry flavor or licorice flavor. Strobel *et al.* disclosed that such water can be fed to all forms of domestic animals or livestock, such as, pigs, cattle, poultry especially chickens and turkeys, horses, sheep, dogs, cats and the like. See second and third full paragraphs in column 5; and Examples 1-3.

Collins *et al.* expressly taught or suggested that vaccine solutions can be suitably flavored with various *known agents* to promote the uptake of the vaccine orally by animals (see last full paragraph in column 5).

Given Collins' express teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to include Strobel's step of adding a palatable strawberry flavor to Bricker's drinking water vehicle that comprises the *Erysipelothrix rhusiopathiae* oral vaccine to produce the instant invention, with a reasonable expectation of success. One of skill in the art would have been motivated to produce the instant invention by suitably flavoring Bricker's oral bacterial composition by adding Strobel's palatable strawberry flavor for the expected benefit of favorably promoting the uptake of Bricker's *Erysipelothrix rhusiopathiae* oral vaccine by animals as taught by Collins *et al.* The rejection stands.

With regard to Applicants' arguments on art rejections in the instant application, it should be noted that what would reasonably have been known and used by one of ordinary skill in the art need not be explicitly taught. See *In re Nilssen*, 851 F.2d 1401, 7 USPQ2d 1500 (Fed. Cir. 1988). The test of obviousness is not express suggestion of the claimed invention in any and all of

the references, but rather what the references taken collectively would reasonably have suggested to those of ordinary skill in the art presumed to be familiar with them. *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). Obviousness does not require absolute predictability, (see *In re Lamberti*, 192 USPQ 278), but only a reasonable expectation of success (see *In re O'Farrell*, 7 USPQ 2d 1673, Fed. Cir. 1988).

Relevant Prior Art

26) The prior art made of record and not relied upon currently in any of the rejections is considered pertinent to Applicants' disclosure:

- At least since the 1960s, it has been a routine and conventional practice in the art to add a fruity flavoring agent to oral anti-bacterial therapeutic compositions. For example, Nash *et al.* (US 3,224,941) disclosed oral anti-bacterial anti-diarrhoeal therapeutic compositions comprising flavoring agents, such as, orange flavor, strawberry flavor, raspberry flavor, wild cherry flavor, lemon or lime flavor, or vanillin, alone or in combination (see Example 1; and last full paragraph in column 4).

- Paul *et al.* (US 5,419,907) disclosed a method of orally administering a vaccine in a powdered or solution form comprising a killed or attenuated infectious agent. The vaccine can be suitably flavored by various known agents to promote the uptake of the vaccine orally by the pig (see last two full paragraphs in column 4; and paragraph bridging columns 4 and 5).

Remarks

27) Claims 1-10 and 27-30 stand rejected.

28) **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this

final action.

29) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The central Fax number for submission of amendments, responses and papers is (703) 872-9306.

30) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

31) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system. A message may be left on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

June, 2005

S. DEVI, PH.D.
PRIMARY EXAMINER